

REMARKS

This amendment responds to the Office Action dated July 18, 2008. In the Office Action on pages 2-7, the patent examiner rejects claims 22, 25-41 and 43 as being non-patentable in view of certain prior or pre-existing technology or art disclosed in the following reference: U.S. Patent No. 4,458,681 to Hopkins (Hopkins '681).

Although Hopkins '681 and the present invention use the word "clamp," Applicant has amended its claims to refer to "a substantially u-shaped cross section with an open end" which open end fits adjacent the trachea. The open ended u-shape clamp is shown in FIGs. 1, 2, 3, and 4 of the application. The open end is formed between the front side and back side of the clamp stricture.

The differences between Hopkins '681 and the present invention (including both Hopkins iterations) are dramatic, as further described herein, and the deficiencies in Hopkins '681 are evident since the Hopkins device has yet to be effectively demonstrated since its disclosure in 1984.

The differences in the claimed invention, compared to the Hopkins '681 devices, begin with the design concepts, and continue through to the strategic placement of the front side and back side members thereby forming a u-shaped clamp with an open end, and finally culminate with how the two products function, (including the features of the claimed invention that will allow it to be mechanically adjustable, possibly even by remote means).

Regarding the design differences, the Hopkins device has two flattened pieces that are screwed together at two distal locations, which extend beyond the perimeter of the stomach on both ends (not the least bit convenient when considering the bulk of the device, and its intervening design flaw when trying to incorporate the device within the limited space provided in the stomach and abdominal cavity). Hopkins '681 clearly shows screws at both ends of the front and back plate

members.

Hopkins '681 also teaches that the device, by design and necessity, is placed across the full length of the stomach (and even extends beyond for the fastener portion and margins of the stomach).

In contrast, the claimed invention is designed to only be placed over a portion of stomach surface, and has, in a specified embodiment, in all, four distinct pieces, including a hinged connection piece that marries the two compression, flattened pieces, and another stabilizing piece that again marries the two flattened pieces. The hinge piece has been further designed to allow for the mechanical adjustment of the pressure the two flattened pieces place on the stomach surface (including the possibility of incorporating a stepper motor, which would allow such adjustments to be made by remote telemetry).

As for the stomach positioning, Claim 22 recites:

wherein the clamp has a substantially u-shaped cross section with an open end for fitting adjacent to the trachea side of the upper quadrant of a stomach, with said front side member and said backside member forming a substantially continuous clamping of the stomach so as to form a canal within the stomach that is an extension of the esophageal canal for regulating nutrient absorption and caloric intake by reducing the capacity of the stomach

Claim 22.

Claim 33 recites:

wherein the device has a substantially u-shaped cross-section with an open end for positioning adjacent to the trachea side of the upper quadrant of a human stomach, with said front side member and said backside member forming a substantially continuous clamping of the stomach so as to form a canal within the stomach that is an extension of the esophageal canal to limit the rate of flow of ingested material into the stomach and to limit the digestion and absorption of the ingested material

Claim 33.

Hopkins '681, as shown in FIGs. 5 and 8, extends over and across the full length of the stomach, does not have a u-shaped clamp with an open end and the closed end of the clamp is not

placed adjacent the trachea side of the upper quadrant of the stomach “to form a canal within the stomach that is an extension of the esophageal canal.”

The claimed invention specifically recites: “a substantially u-shaped cross section with an open end for fitting adjacent to the trachea side of the upper quadrant of a stomach” and wherein the clamp “form[s] a canal within the stomach that is an extension of the esophageal canal” (claim 22, see also, claim 33). FIG. 8 in Hopkins ‘681 does not have a u-shaped cross section with an open end which permits the clamp to fit adjacent the trachea forming a canal within the stomach that is an extension of the esophageal canal. There is no “adjacent the trachea” to “form a canal within the stomach that is an extension of the esophageal canal.” In the present invention, the clamp is an open ended u-shaped clamp and this open ended u-shaped clamp permits the clamp to fit adjacent the trachea forming an extension of the esophageal canal.

In Hopkins ‘681, the circular space about element 18 first is not a u-shaped clamp “fit adjacent the trachea” and second there is no “extension of the esophageal canal” formed by the circular space about element 18. Hopkins ‘681 does not show an “extension of the esophageal canal.” The claimed “extension of the esophageal canal” specifically defines an elongated passageway which extends approximately from the esophageal canal. The clamp of the present invention is u-shaped and its closed end is placed “adjacent the trachea” in such a manner to form the claimed “extension of the esophageal canal.”

As for the adjustment of the present invention, claim 22 states: “the connector comprising a clamp adjusting mechanism for adjusting the distance between said front side member and said backside member” and claim 33 recites “a clamp adjusting mechanism for adjusting the distance between the front side member from the backside member such that the device can be positioned

over the stomach of a patient with the front side member over a front side of the stomach and the backside member positioned over the backside of the stomach, and the stomach will be constricted between the front side member and the backside member.”

Hopkins ‘681 has no clamp adjustment for adjusting the distance between the front side member and the back side member.

Regarding the placement of the Hopkins invention, it is required by its design to fit across a full cross-section of the stomach, including protruding beyond the bounds of the stomach wall (with its fastening portion) to allow the device a place to fasten it together (on both sides).

In contrast, the claimed invention device does not protrude beyond the bounds of the stomach, but in fact, does not even extend to the full length of the stomach cross-section it has been affixed to. Claim 22 recites: “wherein the clamp has a substantially u-shaped cross section with an open end for fitting adjacent to the trachea side of the upper quadrant of a stomach” and claim 33 recites “wherein the device has a substantially u-shaped cross-section with an open end for positioning adjacent to the trachea side of the upper quadrant of a human stomach.”

The claimed invention does not require any such screw fasteners 14 as in Hopkins ‘681 to hold it in its designed resting place on the stomach.

The Hopkins ‘681 disclosure also teaches that the device was designed to be placed perpendicular to the esophagus, as the product was designed to bisect the stomach into two pouches wherein the top pouch receives food entering the stomach, and the bottom pouch where the food eventually ends up (and ultimately exits the stomach) after passing through the orifice created by the two Hopkins clamped pieces. See Hopkins ‘681 col. 1, line 30; and col. 2, line 16 (upper and lower, proximal and distal pouches).

In contrast to the Hopkins '681 devices, the claimed invention is designed to be placed adjacently and vertically to the imaginary line of the esophagus, and is not designed to fully bisect the stomach at all. Claims 22 and 33 recite clamping of the stomach “so as to form a canal within the stomach that is an extension of the esophageal canal.” Hopkins '681 does not form the extension of the esophageal canal.

Finally, it is clear from Hopkins '681, that the devices therein were designed to force any food ingested to go through the orifices created by the devices (in either of the iterations shown in the Hopkins '681 disclosure). See the passage about loop-space 18 in FIGs. 9 and 8; and see the displacement space 36 in FIG. 5 wherein the cross bars are uniformly spaced apart per FIG. 6 (FIG. 6 is a side elevational view of FIG. 5 per col. 1, line 63).

These features of the Hopkins design, are perhaps, the most problematic, as the Hopkins product has no adjustability after implant, and the probability that large food pieces could get lodged in the artificial orifice, or the entry area to the artificial orifice, created by the Hopkins device, is quite substantial, and is probably the main reason the Hopkins product has yet to be demonstrated as effective in any substantive or published clinical trials on animals or humans. The Hopkins clamp is a very substantial barrier to the lower part of the stomach it is bisecting (and therefore, the point of egress from the stomach itself), and would likely become a point of distress for any individual who attempted to use it.

In contrast, the presently claimed invention was designed, not to force any food ingestions to pass through a rigid artificial orifice created by the product, but to only guide the food through “an extension of the esophageal canal” created adjacent to the device, which should serve to avoid the problems prospectively caused by the artificial barrier created by the Hopkins product.

